

REMARKS

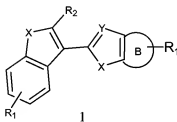
Status of the Claims

Claims 1-17 were originally filed. In the Preliminary Amendment, Claims 18-20 were added. Claims 1-20 were then the subject of a Restriction Requirement mailed January 28, 2008. In Response to that Restriction Requirement, Applicants filed an Amendment on April 28, 2008, where Claims 21-38 were added and amendments to the specification and abstract were made. A subsequent Restriction Requirement acknowledged the Amendment of April 28, 2008, but did not specifically state whether the amendments made therein were in fact entered. In the Response filed August 15, 2008, Applicants proceeded on the assumption that the Amendments in the April 28, 2008, Response were in fact entered; Applicants then canceled Claims 1-20, amended Claims 26 and 37, and added Claim 39. In the current Response, no amendments have been made.

Claims 23 and 28-38 have been withdrawn from consideration by the Examiner, leaving Claims 21, 22, 24-27 and 39 under examination. Claims 21-39 are still pending.

Rejection under 35 U.S.C. 103(a)

In the current Office Action the Examiner rejected Claims 21-22, 24-27, and 39 as allegedly being unpatentable over WO 2007/78761 to Bannister *et al.* (hereinafter Bannister). The Examiner stated that Bannister teaches compounds of the following general formula:



wherein X can be NH, Y can be N, R₂ can be Me, R₁ need not be present, and B can be a polycyclic cycloalkyl or heteroaryl, or heterocyclic rings *inter alia* (referencing page 18, also claims 1-20). The Examiner further stated that pages 10-11 of the disclosure further define the term heterocyclyl or heterocyclic group to mean phenanthroline.

The Examiner further stated that Bannister teaches several examples wherein R_2 is Me, X is NH, Y is N and R_1 is absent. Although the Examiner acknowledged that Bannister fails to teach a specific embodiment wherein B is phenanthroline, the Examiner stated that phenanthroline is suggested as a possible B ring from a finite number of possible combinations. The Examiner thus concluded that it would have been obvious to one of ordinary skill in the art at the time of the instant invention, to arrive at the elected species with a reasonable expectation for success. The Examiner further stated that one would have been motivated to do so because the elected compound is suggested from a finite number of possible combinations. Applicants respectfully traverse the Examiner's rejection for the following reasons.

As an initial matter, the Examiner has improperly referenced the claims of Banister in lodging the rejection (*see* page 6 of the Office Action where the Examiner referenced "claims 1-20" of Bannister as disclosing a genus of compounds). In *In re Benno* (1985), 768 F.2d 1340, (Fed. Cir. 1985), the Federal Circuit held that it was error for the Patent and Trademark Office to reject a claim in a patent application merely because the subject matter of that claim fell within the broadly-worded claim of a prior art patent. The court explained:

The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses only that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding. While it is true ... that "a claim is part of the disclosure," that point is of significance principally in the situation where a patent application as filed contains a claim which specifically discloses something not disclosed in the descriptive part of the specification (claims being technically part of the "specification," 35 USC 112, 2d par.), in which case the applicant may amend the specification without being charged with adding "new matter," within the meaning of § 132. ... But that is not the situation here. [The claim of the prior art patent] does not disclose any structure additional to what the ... specification discloses.

Thus, to the extent that this rejection relies on the claims of Bannister as a disclosure, from which the Examiner draws a conclusion of obviousness, the rejection is improper.

Additionally, the MPEP at §2141.02 (I) states that: "In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not

whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious *Stratoflex, Inc. v. Aeroquip Corp.* 713 F.2d 1530 (Fed. Cir. 1983); *Schenck v. Nortron Corp.* 713 F.2d 782 (Fed. Cir. 1983)” [emphasis in original]. With respect to the “obviousness of species when prior art teaches genus,” the MPEP indicates that the key factor to determine is whether “it would have been obvious to one of ordinary skill in the relevant art to make the claimed invention as a whole, *i.e.*, to select the claimed species or subgenus from the disclosed prior art genus” (§2144.08 (4)).

The MPEP at §2144.08 (4) goes on to state that to address this key issue all relevant prior art teachings should be considered with focus on size of the genus, express teachings, teachings of structural similarity, teaching of similar properties, predictability of the technology and teaching to support the selection of species or subgenus. Moreover, the MPEP clearly states that the size of the prior art genus should be considered bearing in mind that size alone cannot support an obviousness rejection, *e.g.*, *In re Baird* 16 F.3d 380, 383 (Fed. Cir. 1994) (observing that “it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved”).

Applicants assert that the Examiner has failed to consider the claimed invention as a whole and, as such, has not established a *prima facie* case of obviousness.

Firstly, Applicants strongly assert that possible combinations for the ring system represented by B in the genus disclosed by Bannister is not a finite number as stated by the Examiner. Bannister, in fact, discloses an overly broad genus of compounds of structural formula (I), having a fused ring selected from the group consisting of *monocyclic or polycyclic cycloalkyls, cycloalkenyls, aryls, heteroaryls and heterocyclic rings* attached to the imidazole ring, *wherein the rings comprise from 4 to 8 atoms in a ring structure*. Each of these specified groups in and of itself includes a large number of alternatives. By way of example, the disclosure on pages 10-11 of Bannister provides what is acknowledged to be a non-exhaustive list of exemplary heterocyclyl/heterocyclic groups, which includes over 50 different alternatives, without taking into account the different options described for the number of rings or the different options described for ring size. The definition of polycyclyl/polycyclic groups also provided on pages 10-11 is

even broader. When all of the various options for each of these recited groups is taken into account, therefore, the number of possible combinations for the fused ring in fact begins to approach the incalculable.

Second, the exemplary and preferred embodiments of Bannister are directed to “indolyl-benzimidazole” compounds only. Applicants assert that the exemplary and preferred embodiments of Bannister are thus compounds wherein B is a specific type of “monocyclic ring,” rather than the polycyclic ring required by the compounds of formula (VI) of the presently claimed invention.

Furthermore, Bannister fails to provide any guidance or express teaching with respect to compounds having a fused ring other than a “benzene ring” attached to the imidazole group. As such, the cited reference does not teach or suggest the compounds of the instantly claimed invention. Moreover, Applicants note that the disclosed properties of the compounds in Bannister are their antibacterial and/or antiinfective effects. Nothing in Bannister teaches or even suggests that any of the described compounds would be effective anti-cancer agents.

Applicants assert, therefore, that there is nothing in Bannister that would motivate a worker skilled in the art to select the fused ring system having a polycyclic ring as specifically defined in structural formula VI of current claims 21 to 39 and have a reasonable expectation of successfully arriving at the presently claimed compounds that exhibit anti-cancer activity.

In view of the foregoing, Applicants respectfully submit that claims 21-22, 24-27 and 39 are not obvious in light of Bannister, and therefore respectfully request that the Examiner withdraw this rejection.

Double Patenting

The Examiner has provisionally rejected Claims 21-22, 24-27 and 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 25 and 42 of the copending Application No. 10/525,690 and Claims 1-55 of the copending Application No. 11/915,257. Applicant acknowledges the rejection and will formally respond in the appropriate application once claims are found to be allowable, necessitating the removal of the provisional status of the rejection.

Other Matters

The Examiner is requested to acknowledge and confirm that the amendments to abstract and page 29 submitted with the Applicants' Response filed on April 28, 2008, have been made of record. The Office Action acknowledged that the claim amendments made in that Response were entered but did not acknowledge that the amendments to the specification and abstract were likewise entered.

The Examiner is reminded that in order to retain the right to rejoinder for the unelected process claims, the process claims must be amended during prosecution to require all the limitations of the product claims. In this regard, we note that Claim 28, directed to a method of treating cancer, refers directly to the compounds of currently pending product Claim 21. Applicants have further amended dependent method claim 37 to reflect the amendments made to dependent product Claim 26. As such, pharmaceutical composition Claim 27 and method Claims 28 to 39 are in order for rejoinder with the currently pending product Claims 21 to 26.

Finally, the Examiner indicated that the Information Disclosure Statement submitted on November 15, 2006 (received on November 17, 2006) was considered. (Office Action at page 4). Thus, References A1-A13 on Applicants' Form 1449 was initialed and returned to Applicants. Applicants note, however, an Information Disclosure Statement was also submitted December 11, 2008 (references B1-B85 on Applicants' Form 1449). Acknowledgement and consideration of this IDS, along with an initialed Form 1449, is requested.

CONCLUSION

In light of the arguments presented above, the claims are believed to be in condition for allowance. Accordingly, notification of same is earnestly requested.

No fees are believed due; however, the Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence – including any items indicated as attached, enclosed, or included – is being transmitted by EFS-WEB on the date indicated below.

/Christopher L. Curfman/

March 9, 2009

Christopher L. Curfman

Date: